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(54) Stent and method for manufacturing such a stent

(57) A prosthetic stent with a tubular wall (1) having local inwardly or outwardly formed elevations (7) is presented. Stents having such elevations (7) have a higher mechanical stability if bend according to the curvature of the body vessels to be supported or repaired. Also a method for manufacturing a stent with such elevations (7) is described.

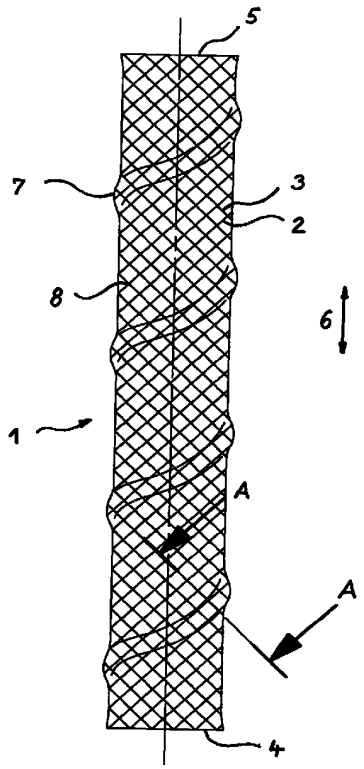

FIG. 1

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Description

The present invention relates to a stent for use in a body passageway, comprising a flexible self-expanding braided tubular wall being composed of helically wound wires and having proximal and distal ends. The invention also relates to a method for manufacturing such a stent.

A stent of the type as mentioned in the introduction is described for example in US patent No. 4,655,771. The tubular wall is composed of several flexible thread elements each of which extends along a helix with the center line of the tubular wall as a common axis. The thread elements are arranged in two groups of opposite directions of winding crossing each other in a way to form a braided configuration. This is to impart to the tublar body the necessary stability for supporting a vessel. The diameter of the tubular wall can be changed by axial movement of the ends relative to each other. The stent is transluminally inserted into postion in its radially compressed state and then subjected to expansion staying in place by a permanent pressure against the inner wall of the body passageway. The stability of the tubular body depends in general from the number of the thread elements, their diameter and material and from the braiding angle of the thread elements at their crossings. It is preferred to have the axially directed braiding angle being obtuse, i.e. larger than 90°, in order to obtain a large force in radial directions. But the braiding angle also influences the shortening of the stent, which is the reduction of the stent length upon conversion from its compressed to its expanded state. At a given diameter expansion the stent shortens less at braiding angles smaller than around 120° than at larger angles.

In the following stents with a braiding angle larger than about 120° are referred to as „normal-shortening" whereas stents having a braiding angle of less than about 120° are referred to as „less-shortening". It is an advantage of less-shortening stents that they can be placed more accurately because the practitioner can better estimate the final positions of the stent ends after expansion. The less-shortening feature comes also to fruition when the stent is implanted in a moving hollow organ in which the stent is repeatedly radially compressed, such as in the oesophagus, in the trachea or in a pulsating blood vessel. In those cases the reduced shortening of the stent is less traumatic for the inner wall of the hollow organ since the stent ends perform smaller axial movements than normal-shortening stents do. For the aforesaid reasons less-shortening stents are preferably implanted in ostium regions, for example in the aorta next to the entries into the renal arteries or in side branches. Exact placement capability and less axial movement of the stent ends reduce the risk of unwanted perturbation or obstruction of the blood flow by stent ends projecting into the ostium.

However, stents of the less-shortening type comprise smaller hoop strength compared to normal-shortening prostheses due to their smaller braiding angle. A consequence of the lower radial force is a reduction of the self-fixation characteric with the risk of a local axial displacement of the stent within the body passageway. Moreover, the stent is not stable enough to resist flattening if it is implanted in arched vessels. This means that a more or less strong deformation of the stent cross-section deviating from its original circular shape can partially close the stent.

In EP-A-0 775 471 an improved stent is disclosed comprising a flexible self-expanding braided tubular wall having a proximal segment of smaller diameter and a distal segment of larger diameter and in-between an intermediate segment forming a truncated cone. A covering layer is arranged within the tubular wall. Although the document does not disclose any specific braiding angles the proximal segment will have a similar braiding angle as the above described less-shortening stent and the distal segment will have a larger braiding angle. The different geometry can be derived from the manufactering methods as described in the document. The large-diameter segment serves as a migration anchor while the less-shortening segment with smaller diameter makes an easier and safer way through curves or at the end of for example a food pipe. But the less-shortening stent segment still has not sufficient shape stability for use in curved areas of body vessels. The cross-section of this segment may be deformed elliptically if bended in curved body vessels as it will occur generally for less-shortening stents. Moreover, because of the conical shape such a stent can be used only at particular areas, such as in food pipes. In addition, it is to be said that the used manufacturing methods are quite expensive.

It is therefore an object of the present invention to improve a less-shortening stent such that it can be used universally, and more specifically in moving and/or in curved body passageways avoiding migration and flattening deformaton thereof. A further object of the invention is to provide a stent which can be manufactured easier.

To this effect, the invention complies with the definitions and features as given in the claims.

The term „elevation" has the meaning of an impression or bulge of the stent wall as well in the negative as in the positive sense, i.e. extending inwardly or outwardly of the tubular stent wall. Accordingly, the tubular wall has at least a local inwardly and/or outwardly formed elevation, whereby the wires are plastically deformed in a way that the number of degrees of freedom for their movement within the braiding is reduced. This means thet the mesh cells defined by the braided wires are „frozen" by a reduced capability of the wires to rotate and shift relative to each other at their crossing points. The braided tubular wall remains its less-shortening feature and becomes more stable against radial deformation. A further advantage of the formed elevations is the possiblility to make a short stent of the type mentioned in the introduction. Such stents are usually

cut from the braiding blank and comprise an unwanted conical shape due to a memory effect from the braiding process. This shape can be converted into a cylindrical tube and conserved by forming elevations on the stent wall.

Where the elevations are distributed regulary over the tubular wall, the stent will be anchored firmly with the tissue of the body vessel without damaging. The homogeneity of the elevation distribution is for example preferred if the stent is to be implanted in a curved area of a body passageway.

More dense distribution of the elevations at the proximal and distal ends of the stent will provide higher stability at these areas for better anchoring thereof with the tissue of the body vessel. This embodiment is preferred if the stent is to be implanted in ostium positions for a safe fixation of the stent ends in order to prevent migration of the stent and disturbing for example the blood flow into a side branch through this ostium. Another preferred application of such a stent is the support of a vessel having a hard plaque stenosis whereby the stent comprises a higher density of elevations in the stenotic region.

In a preferred embodiment of the invention the elevations are formed outwardly so that they can serve as an anchor against stent migration by engaging into the inner vessel wall to be supported. Moreover, the deployment of such a stent with delivery devices as known in the art is enhanced since the retraction of the outer sheath is easier. This results from a reduced friction between the inside of the delivery sheath and the radially outwardly pressing stent touching the sheath only at the elevations.

In another preferred embodiment of the present invention the local elevations have an elongate shape which makes the manufacturing of such stents very easy by using wires to emboss the tubular wall. The elevations may have an arched cross-sectional shape. Preferably the height of the elevations are approximately one to two times the wire diameter of the braid.

These embossments or elevations can be formed helically on the tubular wall, where in a preferred embodiment the helical elevation has a different pitch than the wires of the braid in order to deform a much wires a possible. The elevations may also be formed annularly or in axial direction on the tubular wall depending on the desired effect. Where the elevations are placed annularly the stent wall comprise an improved radial stability, whereas elevations in axial directions impart to the stent a higher longitudinal stability which is especially useful for implantation in the airways.

The manufacturing method according to the present invention is determined by the steps of forming an elongate mandrel having at least one local outwardly bound elevation, forming an elongated tublar braid of spring steel having proximal and distal ends and an inner diameter commensurate with the diameter of the mandrel, engaging said tubular braid over said mandrel, heating the tubular braid on the mandrel, cooling the tubular braid and disengaging the braid from the mandrel. Preferrably previous to the disengaging step the braid will be compressed in axial direction.

These and other objects, features and advantages of the present invention will become readily apparent from the subsequent description, wherein the invention will be explained in further details with reference to the accompanying drawings which show, diagrammatically and by way of example only, preferred but still illustrative embodiments of the invention.

Fig. 1 shows a stent with a helical elevation in side view,

Fig. 2 shows a cross-sectional view according to line A-A in figure 1,

Fig. 3 shows a stent with a plurality of radial elevations in side view,

Fig. 4 shows a stent with a plurality of axial elevations in side view, and

Fig. 5 shows the stent of Figure 4 in front view according to arrow B.

In the following description of the drawings the same reference numbers have been used for all figures if not mentioned otherwise.

The stent depicted in Figure 1 comprises a flexible self-expanding braided tubular wall 1 which is composed of a first plurality of parallel spring stainless steel wires 2 helically wound in a first direction crossing a second plurality of parallel spring stainless steel wires 3 helically wound in a second direction opposite to the first one. The braided structure assures contraction of the stent in the radial direction when the proximal and distal ends 4 and 5 of the stent are pulled away from one another as exemplified by arrows 6, and self-expansion of the stent in the radial direction when the pull according to arrows 6 is released. This configuration is well known in the art and needs no further explanation. Of course, other known braidings or patterns providing the same effect may be used.

The tubular wall 1 of the stent having a helical elevation 7 which is outwardly formed and has an angle of gradient or pitch slightly smaller than the angle of gradient or pitch of the steel wires 3 showing in the same winding direction. The elevations 7 have an elongate and arched cross-sectional shape. The height of the elevations 7 over the tubular wall 1 is about once or twice the diameter of the wires 2 or 3 of the braided configuration. The wires 2 and 3 may be made of a metallic material, e.g. stainless steel, which may be filled with a radiopaque core, or made of a thermoplastic polymer, such as polyesters, polyurethanes, polycarbonates,

polysulphides, polypropylene, polyethylene or polysulphonates. Normally the diameter of the wires 2 and 3 lie within the range 0.01 to 0.5 mms. The helical elevation 7 provides a greater stability of the meshes of the braided tubular wall 1, i.e. the parallel wires 2 and the parallel wires 3 will be prevented from moving apart at the crossing points 8. Especially in the cross-sectional view of Figure 2 it can be seen that wires 2 and 3 have been deformed locally in a tubular shape. The elevation pattern is normally distributed in a regular manner over the tubular wall 1. Therefore a specific wire 2 or 3 will have several elevation areas over its whole length within the tubular wall 1 and a much greater stability of the wires 2 and 3 within the braid will be obtained. The elevation is further smooth curved, i.e. having a continuous smoothly inclining and declining curvature with the effect that the spring activity of the wires 2 and 3 will be reduced in the areas of the elevations. On the other hand the braiding angle between the wires 2 and 3 will be enlarged locally in the area of the elevations which will additionally enhance the mechanical stability of the tubular wall 1. In fact, the meshes are immobilized or „frozen" at the crossing points of the wires 2 and 3 in the area of the elevation. By the frozen meshes the tubular wall 1 will obtain an enlarged shape stability which will resist the deforming forces of the body vessel. The elevation 7 will also reduce the tendency of the wires 2 and 3 to debraid at the proximal and distal ends 4 and 5 of the tubular wall 1. Thus the aforementioned stent will have a greater form or shape stability if the tubular wall 1 will be bent in blood vessels with a strong curvature, i.e. the circular cross-section of the tubular wall 1 will be remained and not deformed to an elliptical one as can be observed with less-shortening stents.

Another possibility of providing elevations for stents according to the present invention is shown in Figure 3, where the stent having annular outwardly formed elevations 12 which are equidistant and parallel to each other. Here also the stability of the stent has been improved over the well-known stents. If an annular elevation 12 will be provided near the proximal and distal end 4 and 5 the tendency of debraiding of the wires 2 and 3 can be reduced further.

In Figure 4 another example of a stent according to the invention is shown, wherein outwardly elevations 13 are provided in axial direction on the tubular wall 1, which elevations 13 are also equidistant and parallel to each other. The front view of Figure 5 shows that these elevations are also smoothly curved as in the previous examples. Since the wires 2 and 3 are intertwined with a relatively dense mesh the four elevations 13 as depicted in this example are sufficient to prevent debraiding at the proximal and distal ends 4 and 5 of the stent.

Although the elevations 7, 12 and 13 in the examples of figures 1, 3 and 4 are formed outwardly on the tubular wall 1, they may also be formed inwardly on the tubular wall 1 or possibly provided in combination of outwardly and inwardly formed elevations.

The manufacturing of the aforementioned stents is as follows:

Firstly the stent will be produced in the known manner, i.e. the wires 2 and 3 will be intertwined with a predetermined braiding angle and with a predetermined mesh size dependent from the wire cross-section. The braiding angle of the so formed stent will normally be between 100° and 120°. Thereafter the stent will be pushed over a cylindical mandrel with a regular pattern of outwardly formed elevations like the helical shape of wires provided on the surface of the mandrel as will be used to form a stent according to Figure 1. The mandrel with the stent will then be heated up to process temperature, kept under process temperature for a certain period of time, and cooled down afterwards. The heating and cooling procedure is carried out under vacuum condition. In the case of stainless steel wires the thermal treatment maybe take up to sixteen hours, whereby the process temperature of 550 °C is maintained for about two hours. Then the stent will be pulled from the mandrel. In cases where the elevations are not axially directed as for the stent depicted in Figure 4, the tubular wall 1 may be compressed in order to enlarge the diameter thereof for an easier disengagement. In case of the helical shape of the elevations the stent may also be unscrewed from the mandrel.

Although other patterns of elevations may also be used for the stents according to the invention the shown patterns are preferred since they guarantee a smooth outer surface of the tubular wall 1 which is especially important for stents to be used at delicate areas such as blood vessels in order not to

Claims

1. A stent for use in a body passageway, comprising a flexible self-expanding braided tubular wall (1) being composed of helically wound wires (2; 3) and having proximal and distal ends (4; 5), characterized in that the tubular wall having at least a local inwardly and/or outwardly formed elevation (7; 12; 13).

2. A stent according to claim 1, wherein the local elevations (7; 12; 13) are distributed regularly over the tubular wall (1).

3. A stent according to claim 1, wherein the local elevations (7; 12; 13) are distributed more densely at the proximal and distal ends (4; 5).

4. A stent according to one of the claims 1 to 3, wherein the local elevations (7; 12; 13) are formed outwardly.

5. A stent according to one of the claims 1 to 4, wherein the local elevations (7; 12; 13) having an

elongated shape.

6. A stent according to claim 5, wherein the elevation (7; 12; 13) having an arched cross-sectional shape.

7. A stent according to claim 6, wherein the elevation (7; 12; 13) having a height of approximately one to two times of the diameter of the wires (2; 3).

8. A stent according to one of the claims 5 to 7, wherein the elevation (7) being formed helically on the tubular wall (1).

9. A stent according to claim 8, wherein the helical elevation (7) having a different pitch than the wires (2; 3) of the braid.

10. A stent according to one of the claims 5 to 7, wherein the elevation (12) being formed annularly on the tubular wall (1).

11. A stent according to one of the claims 5 to 7, wherein the elevation (13) being formed in axial direction on the tubular wall (1).

12. A method for manufacturing the stent according to claim 1, characterized by the steps of:

- forming an elongated mandrel having at least one local outwardly bound elevation,
- forming an elongated tubular braid of spring steel having proximal and distal ends (4, 5) and an inner diameter commensurate with the diameter of the mandrel,
- engaging said tubular braid (1) over said mandrel,
- heating the tubular braid (1) over the mandrel,
- cooling the tubular braid (1), and
- disengaging the braid (1) from the mandrel.

13. Method for manufacturing according to claim 12, wherein previous to disengaging of the braid from the mandrel said braid being compressed in axial direction.

14. Method for manufacturing according to claim 12 or 13, wherein the steps of heating the tubular braid (1) over the mandrel and cooling the tubular braid (1) are performed under vacuum condition.

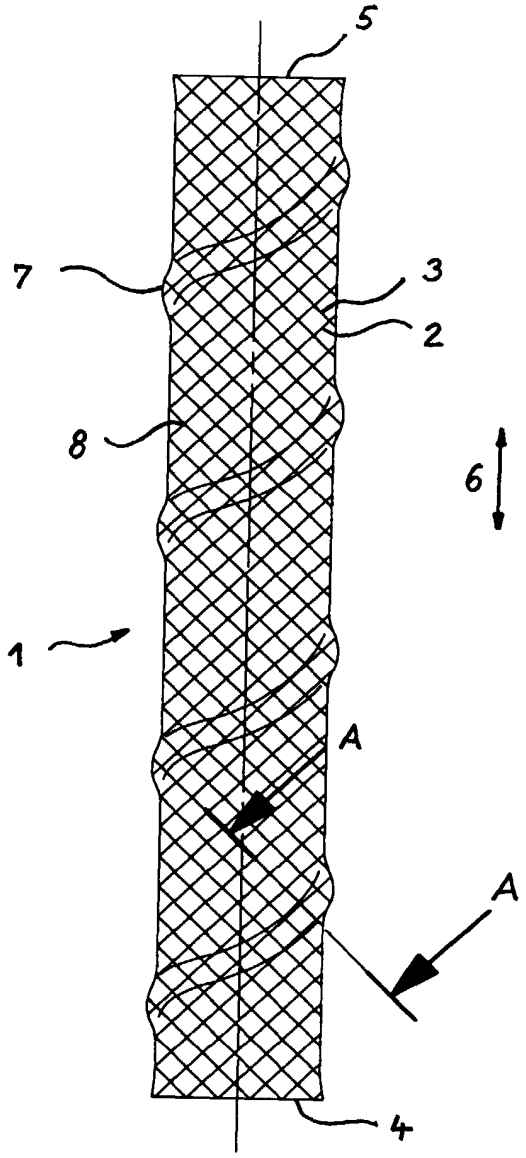

FIG. 1

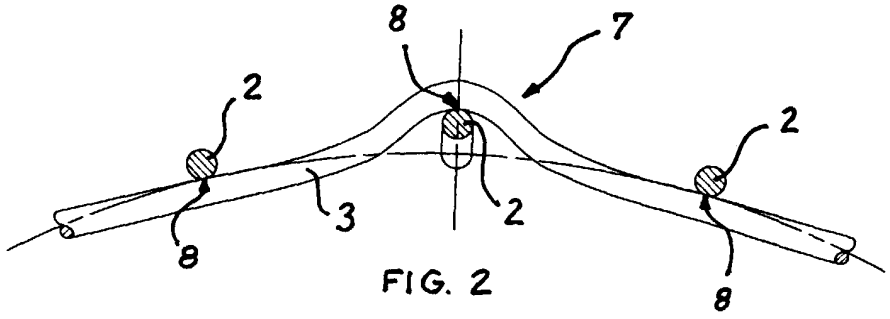

FIG. 2

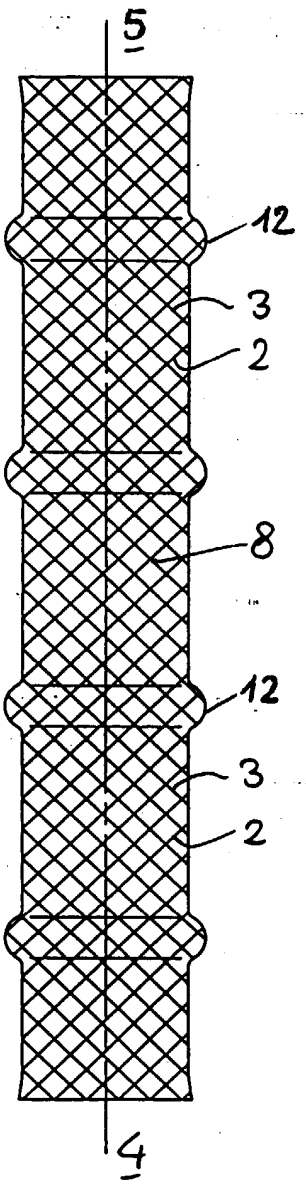

Fig. 3

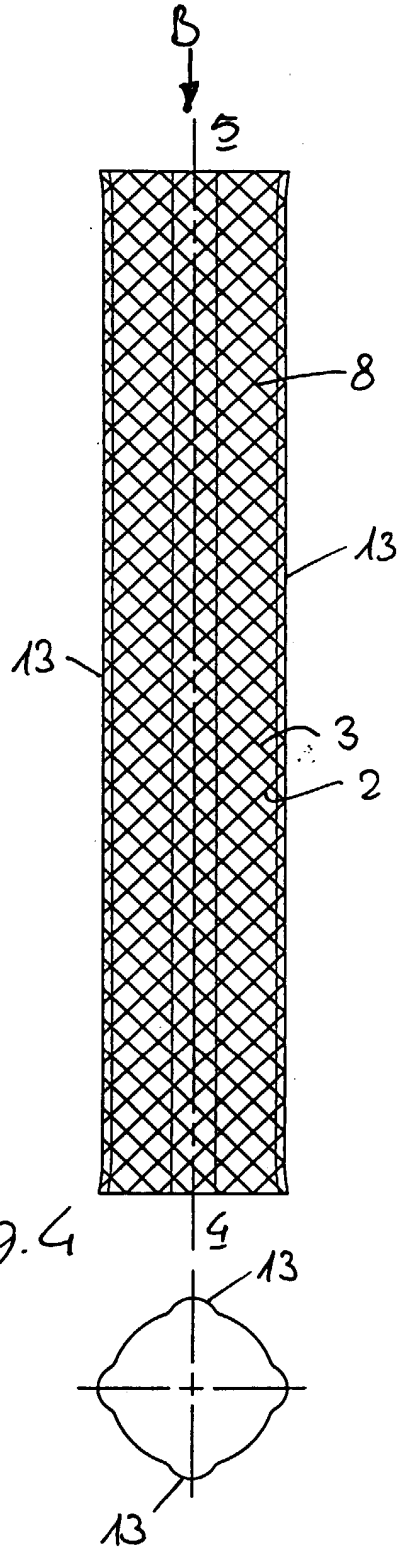

Fig. 4

Fig. 5

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 97 20 2152

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X A	WO 96 29955 A (ANEURX, INC.) * page 15, line 18 - page 16, line 28; figures 1-8 *	1,2,4,5, 10 12	A61F2/06
A	WO 96 25124 A (CORVITA CORPORATION)		

TECHNICAL FIELDS SEARCHED (Int.Cl.6)

A61F

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	17 December 1997	Smith, C

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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